U.S. Provisional Application No. 60/432,932

# EFFICIENT DYNAMIC STIMULATION IN IMPLANTED DEVICE

## FIELD OF THE INVENTION

The present invention relates generally to electrical pulse generators, and specifically to pulse generators for electrical stimulation of tissue.

## BACKGROUND OF THE INVENTION

Stimulation of tissue of a subject, typically a muscle, by applying an electrical potential to the tissue is well known in the medical art. Levels and type of stimulation used depend on a number of factors, such as whether the stimulation is applied externally, and the desired effect of the stimulation. When the tissue is stimulated directly, by one or more electrodes implanted in the tissue, levels of stimulation needed to achieve a specific desired effect are typically orders of magnitude less than the levels needed if the tissue is stimulated externally and/or indirectly. Devices for direct tissue stimulation, such as cardiac pacemakers, are typically implanted into the subject, and typically rely on an internal battery for producing their pulses.

Different types of pulses are known in the art for producing muscle stimulation. In the specification and in the claims, a biphasic pulse is assumed to be a pair of pulses having alternating positive and negative potentials, the biphasic pulse being able to stimulate the tissue; a mono-phase pulse is assumed to be a single uni-directional pulse which is able to stimulate the tissue; and alternating pulses are assumed to comprise a sequence of mono-phase pulses having alternating positive and negative potentials, each mono-phase pulse being able to stimulate the tissue. Typically, a time period between the pair of pulses comprising a biphasic pulse is of the order of 500 μs; a time period between sequential





Applicants: Shai Vangast and Ehud Cohen
U.S. Serial No.: 10/538,521
Filed: as §371 national stage of
PCT International Application No.
PCT/IL2003/001062, filed December 11, 2003
Exhibit 1

alternating pulses is of the order of 25 ms.

U.S. patent 5,391,191, to Holmstrom, whose disclosure is incorporated herein by reference, describes an implanted device for tissue stimulation. The device incorporates a current sensing mechanism which is applied to reduce tissue polarization, electrolysis effects, and detect tissue reaction. The device is implemented to deliver biphasic pulses, as well as a mono-phase pulses. Both types of pulses are used for stimulation; to reduce energy consumption, the device implements the mono-phase pulses.

It will thus be appreciated that efficiency in battery utilization in implanted devices is an important consideration, in order to increase battery life before recharging and/or replacement of the battery is required.

## SUMMARY OF THE INVENTION

It is an object of some aspects of the present invention to provide a method and apparatus for providing pulses for stimulating tissue of a subject.

In preferred embodiments of the present invention, a stimulation device comprises charging circuitry for charging a capacitor to an operating voltage level. Switching circuitry in the device generates both biphasic and alternating pulses, herein termed stimulation pulses, from uni-directional pulses which are generated by discharging the capacitor from the operating voltage level for a pulse period. The stimulation pulses are delivered to tissue of a subject by electrodes implanted therein, generating a tissue stimulation level which is a function of the operating voltage and the pulse period. Initially both the operating voltage and the pulse period are preset by an operator of the device, so as to achieve a desired tissue stimulation level. During operation of the device, a potential is measured on the capacitor at discharge, so as to measure an impedance of the tissue. Responsive to the impedance, the operating voltage level and/or the preset pulse period are adjusted in order to maintain the tissue stimulation level at the desired tissue stimulation level.

The charging circuitry is most preferably driven by an internal battery contained in the device. The circuitry, operated by a micro-controller, comprises a direct current (DC) charging circuit and an alternating current (AC) charging circuit which are each able to charge the capacitor by respective differential potentials. The micro-controller is able to minimize battery energy dissipation by using either or both circuits, and to set the time of use of each circuit in order to charge the capacitor to the initial operating

voltage level. The AC circuit enables the initial operating voltage to be reached regardless of a voltage delivered by the battery,. Similarly, for any adjusted operating voltage or other pulse parameter such as the pulse period, the micro-controller sets the time of use of each circuit so as to charge the capacitor to the adjusted operating voltage efficiently.

Parameters such as tissue impedance and operating voltage level are derived from measured potentials on the capacitor as it discharges. Thus, no current sensing mechanism, as is used by other tissue stimulators known in the art, is required in preferred embodiments of the present invention. Current sensing mechanisms, typically resistors, drain energy. Not implementing such a mechanism achieves a significant saving in energy supplied by a battery powering the stimulation device.

In some preferred embodiments of the present invention, a resistive element having a controlled resistance is coupled between the electrodes so as to be able to short-circuit the capacitor. The resistive element preferably comprises a field effect transistor (FET) having a gate which acts as a control electrode for the resistive element, the gate being activated by a control signal from the micro-controller. By short-circuiting the electrodes and the capacitor at times chosen by the micro-controller, electrolysis effects at the electrodes may be reduced and the tissue stimulation level may be more precisely defined.

In preferred embodiments of the present invention, the micro-controller comprises an analog-to-digital converter (ADC). Most preferably, the stimulation device comprises a calibration circuit which generates a DC reference voltage which is substantially invariant even with variation of battery voltage from a battery powering

the device. A memory in the micro-controller comprises a look-up table which has a one-to-one mapping between a digital value generated by the ADC responsive to the reference voltage and the battery voltage at which the ADC is operating. The look-up table also comprises a one-to-one mapping between the digital value and a multiplicative correction factor. The micro-controller multiplies other digital values, generated as the ADC is measuring voltages within the stimulation device, in order to adjust the other digital values due to changes in the battery voltage.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings, in which:

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic diagram illustrating a stimulation device, according to a preferred embodiment of the present invention;

Figs. 2A and 2B are electronic diagrams of a circuit comprised in the device of Fig. 1, according to preferred embodiments of the present invention;

Fig. 3 shows graphs of voltage versus time for different types of pulses generated in the circuit, according to a preferred embodiment of the present invention;

Fig. 4 shows graphs of voltage versus time for elements of the circuit when one of the types of pulses illustrated in Fig. 3 is generated, according to a preferred embodiment of the present invention;

Fig. 5 is a flowchart showing a process for charging a capacitor in the circuit, according to a preferred embodiment of the present invention;

Fig. 6 is a schematic diagram illustrating an alternate stimulation device, according to a preferred embodiment of the present invention; and

Fig. 7 is a schematic electronic diagram of a calibration circuit, according to a preferred embodiment of the present invention.

## DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Fig. 1, which is a schematic diagram illustrating a stimulation device 10, according to a preferred embodiment of the present invention. Device 10 comprises a circuit 11 which is used to generate electrical waveforms, the waveforms in turn stimulating tissue 20 of a subject 24. Preferably, tissue 20 comprises a muscle, most preferably a sphincter muscle, or a nerve of the subject, although it will be appreciated that tissue 20 may comprise any tissue of subject 24. Device 10 is preferably implanted in the subject, and after implantation and adjustment, is most preferably operated by a control signal generated by subject 24 and input to circuit 11. Circuit 11 may be implemented as discrete components, or as a custom-built component such as an application specific integrated circuit (ASIC), or as a combination of discrete and custom-built components. By way of example, the description hereinbelow applies when circuit 11 comprises discrete components.

Figs. 2A and 2B are electronic diagrams of circuit 11, according to preferred embodiments of the present invention. Circuit 11 is powered by a battery 26, which preferably has a maximum voltage approximately equal to 3.2 V. Circuit 11 comprises a charging circuitry section 13 (Fig. 2A) and a switching circuitry section 15 (Fig. 2B). A micro-controller (MC) 22 acts as an overall controller of circuit 11, using as an input the control signal referred to in Fig. 1. Preferably, MC 22 comprises an XE88LC01 produced by Xemics SA of Neuchatel, Switzerland, although any other micro-controller may be used. MC 22 includes, *inter alia*, a memory 23 wherein parameters for operating circuit 11 may be stored, and an analog-to-digital converter (ADC) 25, which converts

analog voltage levels to digital values.

Charging circuitry section 13 operates in two modes, a direct current (DC) mode and an alternating current (AC) mode. The DC mode is activated when a switching device 17 (Q6) is connected so that a positive terminal of battery 26 is coupled to parallel resistors R19 and R20, each resistor most preferably having approximate values of 150Ω. In the DC mode the positive terminal is de-coupled from resistor R21, which most preferably has an approximate value of 15Ω. Values of resistors R19 and R20 are chosen so as to prevent a current from battery 26 exceeding an allowed maximum battery current value. Switch 17 is most preferably implemented from an FDC6306P produced by Fairchild Semiconductor Corporation of South Portland, Maine and the DC mode is activated by micro-controller 22 enabling control signal STIM_EN1 and disabling STIM_EN2.

In the DC mode, a switch 12 (Q8) - most preferably implemented from a field effect transistor (FET) such as an IRLML2402 produced by International Rectifier Corporation of El Segundo, California - is open, so that battery 26 charges capacitors C13 and C15, which both preferably have a value approximately equal to 22μF, in an RLC circuit formed by resistors R19, R20, an inductor L1, and the capacitors. During operation of circuit 11, the DC mode most preferably operates for a time period, defined by MC 22, no greater than approximately $3 \bullet \tau$ s, where $\tau$ is a charging time constant equal to the RC value of R19, R20, C13, and C15, i.e.,. $75 \bullet 44 \bullet 10^{-6}$. It will be understood that by charging the capacitors for this length of time (when the capacitors start in a completely discharged state), C15 achieves approximately 95% of the potential of battery 26.

The AC mode is activated when switch 17 couples the positive terminal of battery 26 to R21, while R19 and R20 remain coupled as for the DC mode. MC 22 activates the AC mode by enabling control signals STIM_EN1 and STIM_EN2. In the AC mode switch 12 is rapidly switched closed and open by a rectangular signal STIM_SW, generated by the micro-controller, alternating between on and off states. Most preferably, STIM_SW is on for approximately 0.25μs, and off for approximately the same time interval. When switch 12 is closed, inductor L1, preferably having an approximate value of 68μH, is energized by current through the inductor flowing to ground. When switch 12 is open, current from inductor L1 is diverted via a diode D4 to charge capacitor C15. Assuming that a combined resistance of an internal resistance of inductor L1 and switch 12 is approximately 600 mΩ, approximately 99.7% of the current flowing in the inductor charges capacitor C15. Preferably, a switch 19, most preferably a Reed switch, is positioned before capacitor C15 for use as a safety cut-out.

It will be appreciated that operating circuit 11 in the AC mode as described above enables capacitor C15 to be charged to a high voltage, most preferably of the order of 9 V, which is substantially independent of a voltage supplied from battery 26 and which is only limited by the time during which the AC mode is operative. It will also be appreciated that from an energy efficiency point of view, it is preferable to use the AC mode rather than the DC mode for charging capacitor C15. The charging rates for both modes may be calculated from values of elements of circuit 11, including a potential delivered by battery 26, as will be apparent to those skilled in the art. The rates are preferably stored in memory 23. In some preferred

embodiments of the present invention, which mode is used, and for how long the mode is implemented, is a function of a voltage differential to which capacitor C15 is to be charged, respective rates of charging for the DC and AC modes, and a time during which the capacitor is available for charging. A more detailed description of capacitor C15 charging by utilizing stored charging rates is given below.

During operation of circuit 11, micro-controller 22 monitors the voltage across capacitor C15 using resistors R22 and R24 coupled in series across C15, the resistors acting as a voltage divider. The monitored voltage is converted to digital values using ADC 25. Preferably, memory 23 also comprises an ADC look-up table 29, the function and composition of which is described with reference to Fig. 7 below.

In section 15 (Fig. 2B), capacitor C15 is used to generate pulses at a first electrode 28 and a second electrode 30 implanted in tissue 20, via operation of switches 14, 16, and 18. Switches 14 and 18 are implemented as single pole single throw (SPST) switches, preferably integrated load switches FDC6324L produced by Fairchild Semiconductor Corporation, although any other suitable switches may be used. Switch 16 comprises two separate SPST switches 34 and 36, preferably implemented from an integrated load switch FDC6324L, produced by Fairchild Semiconductor Corporation.

Table I below shows states of switches 14, 18, 34, and 36, and respective control signals, as used to generate a positive-going pulse, where electrode 28 is positive with respect to electrode 30, and a negative-going pulse, where electrode 28 is negative with respect to electrode 30.

| Switch | Switch Control | Switch state | |
|---|---|---|---|
| | | Positive-going pulse | Negative-going pulse |
| Switch 14 | STIM_CTRL1 + | closed | open |
| Switch 18 | STIM_CTRL2 - | open | closed |
| Switch 36 | STIM_GND1 + | closed | open |
| Switch 34 | STIM_GND2 - | open | closed |

Table I

Resistors R29 and R33, each approximately equal to 15Ω, respectively act as current limiting resistors for positive-going and negative-going pulses. Current limitation may typically be required in the event of an inadvertent short between electrode 28 and electrode 30.

MC 22 sets switches 14, 18, 36, and 34 according to Table I, in order to produce pulses as required. MC 22 is also able to monitor an impedance of tissue 20, by measuring the discharge of capacitor C15 as pulses are generated in tissue 20, as described in more detail below.

Fig. 3 shows graphs of voltage versus time for different types of pulses generated in circuit 11, according to a preferred embodiment of the present invention. A graph 50 illustrates biphasic pulses 55 generated at electrodes 28 and 30, the biphasic pulses having a period of $\tau_1$. Each biphasic pulse 55 is formed from a uni-directional pulse 54 and a uni-directional pulse 56 which are substantially mirror images of each other, having substantially equal pulse width times $\tau_2$. Pulse 54 is a positive-going pulse having an initial potential $V_{stim}$, pulse 56 is a negative-going pulse having an initial potential $-V_{stim}$. A time $\tau_3$ between pulses 54 and 56 is very much less than the period $\tau_1$ of

the pulses.

A graph 60 illustrates alternating pulses 64 and 66 generated at electrodes 28 and 30, having a period of $\tau_4$. Pulses 64 and 66 are substantially mirror images of each other, having substantially equal pulse width times $\tau_5$. Pulse 64 is a uni-directional positive-going pulse having an initial potential $V_{stim}$, pulse 66 is a uni-directional negative-going pulse having an initial potential $-V_{stim}$. However, unlike pulses 54 and 56, a time $\tau_6$ between alternating pulses 64 and 66 is approximately equal to half the period $\tau_4$ of the pulses.

Most preferably, initial values for $V_{stim}$ and times $\tau_1$, $\tau_2$, $\tau_3$, $\tau_4$, $\tau_5$, and $\tau_6$ are implemented by an operator of device 10, in conjunction with feedback from subject 24, in order to correctly stimulate tissue 20, and the values are stored in memory 23. It will be appreciated that more than one set of initial values of $V_{stim}$ and times $\tau_1$, $\tau_2$, $\tau_3$, $\tau_4$, $\tau_5$, and $\tau_6$ may be stored, and each particular set of values may be implemented by subject 24 or by the operator. For example, if tissue 20 comprises a sphincter muscle of the urinary tract, a first set of values may have $V_{stim}$ equal to approximately 6V, and times $\tau_1$, $\tau_2$, $\tau_3$, $\tau_4$, $\tau_5$, and $\tau_6$ equal to approximately 25 ms, 1μs, 500μs, 50 ms, 1μs, and 25 ms respectively. A second set of values may have $V_{stim}$ equal to approximately 2V, and times $\tau_1$, $\tau_2$, $\tau_3$, $\tau_4$, $\tau_5$, and $\tau_6$ equal to approximately 100 ms, 1μs, 500μs, 200 ms, 1μs, and 100 ms respectively. Micro-controller 22 may use either or both sets, and/or other similar sets of parameters, in order to stimulate tissue 20.

Micro-controller 22 implements both alternating and biphasic pulses by operating switches 17 and/or 12 to charge capacitor C15 to a voltage $V_{stim}$. Once the

capacitor has been charged, switches 14, 16, and 18 are operated, as described with reference to Table I above, to generate the pulses.

Fig. 4 shows graphs of voltage versus time for elements of circuit 11 when the biphasic pulses illustrated in Fig. 3 are generated, according to a preferred embodiment of the present invention. Generally similar graphs of voltage versus time for the elements apply for generation of alternating pulses. Typically, circuit 11 generates a sequence of pulses (biphasic or alternating) on receipt of the control signal (Fig. 2A) at MC 22. Preferably, if tissue 20 comprises a sphincter muscle, the control signal is derived from a pressure sensor activated by subject 24. Most preferably, a level of the control signal is used to determine which type of pulses (biphasic and/or alternating) are produced by circuit 11.

The graphs of Fig. 4 illustrate voltages versus time for capacitor C15 in a period 80 before the capacitor reaches a quasi-steady state, and in a period 82 when the capacitor is in the quasi-steady state. By way of example, $\tau_1$, $\tau_2$, and $\tau_3$ for the biphasic pulses of graph 50 are assumed to be approximately 20ms, 1μs, and 500μs respectively, battery 26 is assumed to supply 3V, and the biphasic pulses have a quasi-steady state amplitude of 3.5V, although it will be appreciated that circuit 11 may implement other values for these parameters.

A graph 70 represents the voltage on capacitor C15. At the beginning of a period 84, at which time circuit 11 is required to generate a biphasic pulse, capacitor C15 has been charged to 3V. The biphasic pulse generated in period 84 causes capacitor C15 to discharge at the end of period 84 to 2V.

At the end of period 84, MC 22 preferably evaluates

periods during which the DC mode and the AC mode are to be implemented. Preferably, the period for the AC mode is made as large as possible, since charging using the AC mode is more efficient than using the DC mode. The evaluation is based on the charging rates for the DC mode the AC mode (stored in memory 23), a desired voltage differential to be achieved, and an available time for charging. Thus, for a time period 86 following period 84, the desired voltage differential is 1.5V and the available time is approximately 20 ms. By way of example, MC 22 is assumed to set a DC mode period 88 of approximately 8 ms, and an AC mode period 90 of approximately 12 ms.

An alternative method by which MC 22 is able to charge capacitor C15 is described with reference to Fig. 5 below.

Voltage waveforms for STIM_EN1, STIM_EN2, and STIM_SW are shown in graphs 92, 94, and 96 respectively. Time period 88 is implemented by enabling STIM_EN1. Time period 90 is implemented by enabling STIM_EN1 and STIM_EN2. During period 90, STIM_SW pulses activate switch 12, as described above, and at the end of period 90 capacitor C15 has charged to 3.5V, so that quasi-steady state period 82 begins.

During periods 98, circuit 11 generates biphasic pulses of amplitude 3.5V, and capacitor C15 discharges from 3.5V to 2.5V. At the end of each period 98, MC 22 preferably makes an evaluation, substantially similar to that described above for the end of period 84, for charging periods 100. Herein MC 22 is assumed to set an AC mode period of approximately 20 ms, so that the DC mode is not implemented for periods 100, as is illustrated by graphs 92, 94, and 96. Alternatively, MC 22 implements the method of Fig. 5 for charging capacitor

C15.

It will be appreciated that by being able to use either or both AC and DC charging modes, circuit 11 is able to reach a quasi-steady state quickly and efficiently, and is also able to maintain the quasi-steady state with a minimal waste of energy. Both factors are important for optimal implementation of battery powered implanted devices delivering sequences of pulses.

Fig. 5 is a flowchart showing an alternative process 101 for charging capacitor C15, before generating pulses 55, 64, and 66 (Fig. 3), according to a preferred embodiment of the present invention. Process 101 does not rely on knowledge of charging rates of the DC and AC mode of circuit 11.

In an initial step 102 of the process, the voltage $V_{out}$ across C15 is measured by MC 22 sampling the potential at the junction of R22 and R24.

In a first decision step 104, MC 22 compares the value of $V_{out}$ determined in step 102 with a limit value which is set to be a function of a voltage delivered by battery 26. Most preferably, the limit value is implemented to be approximately 90% of the battery voltage, although another value, less than the battery voltage, may be used. If $V_{out}$ is greater than or equal to the limit value, process 101 continues to a second decision step 108. If $V_{out}$ is less than the limit value, in a DC charging step 106 the DC charging phase of section 13 is implemented, by setting STIM_EN_1, and ensuring that STIM_EN_2 is not set. DC charging step 106 is activated for a period of approximately 1 ms, after which step 102 is implemented. The process of cycling through steps 102, 104, and 106 continues for up to five times, or until step 104 is not satisfied.

In second decision step 108, MC 22 compares the

value of $V_{out}$ with a required voltage stimulation value $V_{stim}$ stored as described above in memory 23. If $V_{out} < V_{stim}$, then MC 22 initiates an AC charging step 110, during which the AC charging phase of section 13 is implemented, by setting STIM_EN_1 and STIM_EN_2.

During step 110, switch Q8 is toggled between on and off states, as described above. When Q8 is in its off state, MC 22 measures $V_{out}$, as described for step 102. The process of AC charging continues until step 108 is no longer valid, i.e., $V_{out} = V_{stim}$. Alternatively, the AC charging continues until the time at which a pulse is to be generated, corresponding to the end of periods $\tau_1$ or $\tau_6$ (Fig. 3), at which point process 101 terminates.

It will be appreciated that, depending on the differential potential to which capacitor C15 is to be charged, and on the time period available for charging, process 101 may invoke operation of the AC or the DC circuits of section 13, or both circuits.

Returning to Figs. 2A, 2B, and 3, MC 22 measures a potential on capacitor C15 at the end of each pulse. MC 22 uses this value, the initial value $V_{stim}$ of the pulse, and the period $\tau_2$ for biphasic pulses (or $\tau_5$ for alternating pulses), to evaluate an impedance of tissue 20, most preferably from an impedance look-up table 27 stored in memory 23. (MC 22 may obtain values of $V_{stim}$, $\tau_2$ and $\tau_5$ from memory 23.) During periods when MC 22 determines that the impedance of tissue 20 is substantially constant, values of $V_{stim}$, $\tau_2$ and $\tau_5$ are not altered In the event that the impedance does alter, MC 22 most preferably alters the value of $V_{stim}$ so that an average current generated by the pulses is substantially constant. Alternatively or additionally, MC 22 alters the width of the pulses so that the average current is substantially constant. Any altered values are stored in

memory 23, and are used by MC 22 in subsequent pulse generation. Measurements of the impedance, as described above, enable MC 22 to detect open or short circuits, such as may occur by misplacement of one of electrodes 28, 30.

It will be appreciated that both biphasic and alternating pulses generated by preferred embodiments of the present invention comprise sequential pulses which are substantially equal in magnitude but opposite in direction to each other. Thus, charge transfer when the pulses are applied to tissue 20 is substantially equal in magnitude but opposite in direction, so that substantially no electrolysis occurs during stimulation to the tissue. It will also be appreciated that by measuring the impedance of tissue 20 as described above, and by adjusting stimulation parameters responsive to the impedance, there is no need for measuring or estimating current in tissue 20 by a separate current-sensing circuit, as is implemented in systems known in the art for stimulating tissue.

The biphasic pulses described hereinabove, and illustrated in graph 50 (Fig. 3 and Fig. 4), each comprise a positive-going pulse followed by a negative-going pulse. Such a non-alternating sequence of biphasic pulses may be represented as (+-),(+-),(+-),(+-),.... It will be appreciated that the biphasic pulses may each comprise a negative-going pulse followed by a positive-going pulse, which non-alternating sequence may be represented as (-+),(-+),(-+),(-+),.... It will be further appreciated that the biphasic pulses may be alternated in a regular or an irregular sequence, so that alternating sequences of biphasic pulses of the form (+-), (-+), (+-), (-+),(+-),..., or (+-), (+-), (-+), (+-),(+-),..., or of any other regular or irregular sequence may be generated.

The application of alternating sequences of biphasic pulses may reduce electrolysis effects at electrodes 28 and 30 (Fig. 2B). All forms and combinations of non-alternating and alternating sequences of biphasic pulses are assumed to be comprised within the scope of the present invention.

Fig. 6 is a schematic diagram illustrating an alternate stimulation device 150, according to a preferred embodiment of the present invention. Apart from the differences described below, the operation of device 150 is generally similar to that of device 10 (Figs. 1, 2A, 2B, and 3), so that elements indicated by the same reference numerals in both devices 150 and 10 are generally identical in construction and in operation. Device 150 comprises a controllable element 152 which is connected between electrodes 28 and 30, and which is able to act as an effective short-circuit therebetween, responsive to a control signal from MC 22. Element 152 preferably comprises a resistor in series with an FET such as an IRLML2402, or alternatively any other set of electronic components, such as will be apparent to those skilled in the art, which are able to act as a controllable short-circuit.

The control signal for element 152 is input to a control electrode 154 of the element, the control electrode comprising a gate of an FET if element 152 is implemented therefrom. Most preferably, MC 22 activates the control signal directly after a biphasic pulse or an alternating pulse has been impressed on electrodes 28 and 30. By activating the control signal directly after the pulses, and thus short-circuiting the electrodes, the level of stimulation to tissue 20 is more effectively controlled. Furthermore, any residual charge on the electrodes from the pulses charging an effective

capacitance of the electrodes is substantially neutralized, so reducing electrolysis effects at the electrodes.

Fig. 7 is a schematic electronic diagram of a calibration circuit 160, according to a preferred embodiment of the present invention. Circuit 160 is most preferably included in device 10 and device 150, and is used as a reference for correcting inaccuracies in the operation of ADC 25. Apart from the differences described below when circuit 160 is implemented, operations of devices 10 and 150 are generally as described above with reference to Figs. 1, 2A, 2B, 3 and 6.

Implanted devices such as device 10 and device 150 are expected to operate for a number of years before battery recharging, or before device or battery replacement. The device thus needs to operate over relatively large variations of battery voltage. However, the output of analog-to-digital converters such as ADC 25 is not invariant with battery voltage (applied to MC 22 wherein ADC 25 is located) and so a method of correction of any such variation is highly desirable.

Circuit 160 comprises a resistor 164, a zener diode 162, and an FET 170 acting as a switch. The resistor, zener diode, and switch are connected as a series circuit between V+ and V- (Fig. 1). A gate electrode 172 is coupled to a control port of MC 22. Thus, MC 22 may effectively toggle the series circuit on or off, by application of a control voltage to electrode 172. When the series circuit is on, the circuit acts as a voltage regulator supplying a substantially invariant voltage, even with variation of voltage from battery 26, at a junction 169 between the zener diode and resistor 164. Other circuits or electronic devices driven by battery 26, for producing a substantially invariant voltage, will

be apparent to those skilled in the art. All such circuits and electronic devices are assumed to be comprised within the scope of the present invention.

A pair of resistors 166 and 168 are connected in series and shunt zener diode 162, the resistor pair acting as a voltage divider having an output at a junction 167 of the resistor pair. Preferable values for resistors 164, 166, and 168 are approximately 1 kΩ, 100 kΩ, and 100 kΩ respectively, and zener diode 162 preferably has an operating voltage of approximately 1.2 V and a "striking" current of approximately 1 mA. Thus, battery voltages greater than about 2.2 V cause zener diode 162 to strike, and generate a substantially invariant voltage of 0.6 V at junction 167.

The output from junction 167 is fed by an SPDT switch 176 to ADC 25. Switch 176 is controlled by MC 22, and in a first position the switch couples junction 167 to ADC 25. In a second position the switch couples the junction of R22 and R24 to the ADC, as described above with reference to Fig. 2A.

Before operation of device 10 or device 150, ADC look-up table 29 is stored in memory 23. The table comprises outputs of ADC 25 when input with the voltage from junction 167, respective voltages of battery 26, and respective multiplicative correction factors to be applied to the outputs of the ADC. (It will be understood that when battery 26 is operating at its nominal voltage, the output of ADC 25 will be substantially correct, and the correction factor in this case is 1.) Most preferably, the table allows for changes in actual value of voltage input to the ADC due to an internal resistance 174 of the ADC, the internal resistance typically being a value of approximately 150 kΩ.

To calibrate ADC 25 during operation of device 10 or

150, the micro-controller sets switch 176 to be in its first position, and sets FET 170 to conduct so that the voltage of junction 167 is input to the ADC. An output from ADC 25 is recorded by MC 22, and the micro-controller uses table 29 to determine the battery voltage, and to determine the correction factor to be applied to readings derived from ADC 25 due to a change of battery voltage from its nominal value. Most preferably, the battery voltage and the correction factor are determined using linear interpolation of values present in table 29, or by any other method known in the art. As changes in battery voltage occur, MC 22 uses the new values of battery voltage and the correction factor for ADC 25 to ensure that the average current generated by the pulses, described above with reference to Figs. 4 and 5, is substantially constant.

The calibration described hereinabove may be implemented at any convenient time, as determined by MC 22, most preferably when there is no requirement for device 10 or device 150 to generate stimulation pulses. Because of the generally slow rate of change of battery voltage with time, such calibrations will normally only need to be implemented relatively infrequently, such as at 24 hourly intervals. Such a regular calibration time is preferably programmed into MC 22 at installation of device 10 or 150. Most preferably, MC 22 monitors changes in battery voltage as determined by the calibration, and is adapted to change the times of calibration in the event of any relatively sudden change in battery voltage, such as a relatively sharp voltage decrease. It will be appreciated that the calibration system described hereinabove allows for measuring the voltage output from battery 26, as well as correcting for inaccuracies in ADC 25 output due to changes in the battery output voltage

from a nominal output value.

It will thus be appreciated that the preferred embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.